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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/214,155 12/29/98 TAKAYAMA

H 052816

EXAMINER

HM12/0301

SUGHRUE MION ZINN MACPEAK & SEAS  
2100 PENNSYLVANIA AVENUE NW  
WASHINGTON DC 20037-3202

QAZI, S

ART UNIT

PAPER NUMBER

1616

DATE MAILED:

03/01/00

12

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

# Office Action Summary

Application No.

09/214,155

Applicant(s)

Hiroaki Takayama et al.

Examiner

Sabiha Qazi

Group Art Unit

1616



☒ Responsive to communication(s) filed on Dec 30, 1999

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1 and 2 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1 and 2 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☒ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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**Final Office Action on Merits**

**Invention:** *The instant invention is drawn to a vitamin D<sub>3</sub> derivatives having a methyl group at 2-position and 20S isomer. These compounds are useful as a treating agent for osteoporosis.*

**Status of the Application**

Claims 1 and 2 are pending and are rejected.

No claim is allowed.

Applicant,s response and declaration filed in paper no. 9 and 10, dated 12/30/99 is hereby acknowledged. Amendments are entered. Objections over claims 1 and 2 are withdrawn.

**Rejection Maintained**

1. Claim 1 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Miyamoto et al. (US Patent 5,877,168) for the same reasons set forth in office action mailed in paper no. 4, dated 6/30/99.
2. Claim 2 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Trost M. Barry et al. (J. Am. Chem. Soc., Vol. 114, No. 25, (1992), pages 9836-45)for the same reasons set forth in office action mailed in paper no. in paper no. 4, dated 6/30/99.

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### **Response to Arguments**

Applicant's arguments are fully considered but are not found persuasive. Following reasons apply:

#### **Declaration**

1. Declaration is unsigned.
2. The compound numbers cited in the declaration are not explained. It is unclear what compounds are compared. There should be a side by side comparison with closest prior art compound and the instant compound in the form of a declaration. See MPEP 716.02(e).
3. The basis of the arguments is the activity for differentiation HL-60 cell of the instant compounds and the superior activity. Applicants are claiming compounds and their process of making. Since the declaration is not acceptable the issue of the unexpected property cannot be resolved for the reasons cited above.

#### **Basis of rejection**

1. Miyamoto et al. teach vitamin D derivatives with substituents at 2 $\beta$ -position. See formula (I) in col. 2 and lines 33-42, where R<sub>1</sub> represents hydrogen or a hydroxy group and R<sub>2</sub> represents straight chain or branched lower alkyl group having 1-

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7 carbon atoms has been taught. See the entire document especially example 14, where (triethysilyloxy) vitamin D3 derivatives are disclosed.

The instant claims differ from the reference in having a broader generic scope. Prior art teaches (triethylsilyloxy) vitamin D3 analogs whereas instant invention claims (triC1-C7 alkylsilyloxy) vitamin D. Alkyl C1-C7 is broader than ethyl group.

One having ordinary skill in the art would be motivated to prepare additional derivatives of vitamin D<sub>3</sub> by modification in the structure taught by the prior art,

The compounds of Miyamoto et al. are known to have in vitro calcium regulatory activity and differentiation stimulating activity on tumor cells, etc. and are useful as treating agent for diseases caused by abnormal calcium, such as osteoporosis and osteomalacia, or as an antitumor agent. See col. 1, lines 10-19.

There has been ample motivation provided by the prior art to prepare such compounds when searching for new compounds of the similar activity.

Nothing unobvious is seen in substituting the known claimed isomer for the structurally similar isomer taught by US '168 since such structurally related compounds suggest one another and

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would be expected to share common properties absent a showing of unexpected results.

2. Claim 2 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Trost M. Barry et al. The reference teach a palladium-catalyzed alkylative cyclization of enynes for the synthesis of vitamin D derivatives.

The instant claims differ from the reference by employing an analogous starting material which differs in having a methyl group at 4-position of the compound of formula III i.e. in instant claims 4-position is substituted by a methyl group whereas prior art teaches no substituents at this position.

The starting materials are analogous in that they are both are enynes of formula III.

One having ordinary skill in the art would have been motivated to employ the process of the prior art with the expectation of obtaining the desired product because he would have expected the analogous starting materials to react similarly.

It has been held that application of an old process to a analogous material to obtain a result consistent with the

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teachings of the art would have been obvious to one having ordinary skill.

### ***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1 and 2 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 and 2 of copending Application No. 09/09/068219. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims are drawn to structurally similar 2-substituted vitamin D analog having R as tri (C1-C7 alkyl) silyl derivative.

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It was noted by the Examiner that applicant's copending application 09/214,155 contains the same invention as claimed in this instant application 09/068,219. Since there is no mention of the copending application which is drawn to the similar invention, this action is made Final. Double patenting rejection is considered necessary even though the action is made Final.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### **Conclusion**

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing



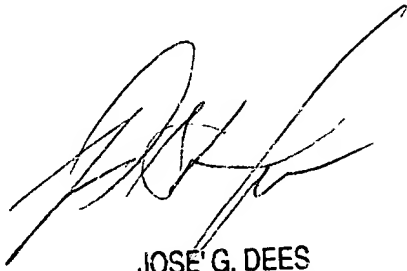
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date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha N. Qazi, whose telephone number is (703) 305-3910. The examiner can normally be reached on Monday through Friday from 8 a.m. to 6 p.m. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

2/26/2000

  
JOSE G. DEES  
SUPERVISORY PATENT EXAMINER  
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